REMARKS

Reconsideration and allowance of the subject application are respectfully requested.

The amendments to the specification at the end of paragraph [0042] and the middle of paragraph [0043] were objected to as entering new matter. This was addressed in the interview wherein the applicant pointed out support for the amendment in the specification as filed. For example paragraph [0015] (sentence 3) reads, "The system also includes a volume reducer, which is configured to induce a reduction in the volume of flush solution within the lock system. In the presently preferred embodiment **the reducer is configured for progressively reducing the internal volume of the tubing system at a plurality of different times** to displace a plurality of fractions of the residual volume into the indwelling portion of the catheter to intermittently flush the indwelling portion with the flush solution." (Emphasis added.) Paragraph [0042] reads "...**each sequential clamp (402 then 403) is closed at 8 hr. intervals to flush the catheter** 409 every shift (this interval may be prolonged with specialized formulations as discussed previously). **After 24 hours or eight hours after the last catheter-flushing clamp has been closed, all the catheter-flushing clamps are opened and the system 400 is "recharged" by flushing the system** 400 with saline through the proximal terminal 406. The system 400 is now ready to provide another 24 hours of sequential catheter flush." (Emphasis added). Therefore at least 3 intervals (to total 24 hours) prior to volume reductions are clearly disclosed.

Paragraph [0043] reads "When this **new method is applied to maintain patency of an indwelling catheter, external flushing need only be applied every 24 hours or even less frequently,** greatly reducing cost and the number of times the system is opened and potentially reducing the infection risk. Deployment of the sequential catheter flush system could, over several years; save a hospital hundreds of thousands of dollars while at the same time reducing nurse workload and patient and nurse infection risk. In many cases the patient may be receiving medication (such as an antibiotic) only every 24 hours, or **the protocol (such as may be applied with PICC catheters) may call for flushing only every 12 to 24 hours.** For these reasons, the sequential catheter flush system according to the present invention can with some patients, eliminate all flushes other than those delivered immediately after antibiotic infusion. Failure rates of lock devices due to delayed or missed flushes may also be minimized by the present invention since the sequential catheter flush system is more easily applied and less time consuming." Therefore the method of maintaining the patency of a lumen of a catheter 24-72 hour since closure of a clamp every 24 hours equals 72 hours.

Paragraph [0023] reads "Then, at a plurality of different times, increasing the pressure within the tubing system, **as by progressively, and in discrete steps, reducing the internal volume of the tubing system, to displace a plurality of fractions of the residual volume into the indwelling portion to intermittently flush the indwelling catheter portion** with the flush solution." Therefore the steps

are clearly supported and it is clear that the second residual volume is less than the first residual volume.

Furthermore paragraph [0023] reads "The reducer and or one of its elements can be a tube compressing member configured for compressing the tubing system to **a plurality of sequentially lower levels of internal volume**, such that each time the system volume is reduced further, an additional portion of the stored residual volume of flush solution is displaced toward the blood-flush solution interface to displace blood which may have invaded the catheter or otherwise diluted or diminished the effect of the antimicrobial or anticoagulant."

Furthermore paragraph [0023] (sentence 3) reads "These catheter-flushing clamps 401,402 and 404 are marked at both the top (thumb contact) surface 415 and the bottom surface with "1st, 2nd, and 3rd" to remind the nurse of **the order of closure every 8 hours** as will be discussed."

Furthermore paragraph [0023] reads "In one example, a catheter-flushing clamp of the type for example shown in FIGS. 2-4 with a compression length of 9 mm mounted on tubing with a internal diameter of about 3.5-4 mm, can generate a flush volume exceeding the entire internal volume of the potential indwelling length 414 of a typical 1.5 inch 18 gauge catheter (as for example the "Insyte" catheter marketed by Becton Dickinson), **so that the sequential closure of each**

of the three such flushing clamps 401,402,403, can achieve complete flushing of the lumen 411 of catheter 409 on three separate occasions without requiring the opening or internal access of the system 400." Clearly the sequential reducing "without refilling" after the first reduction is supported.

Furthermore paragraph [0043] reads "When this new method is applied to **maintain patency of an indwelling catheter, external flushing need only be applied every 24 hours or even less frequently**, greatly reducing cost and the number of times the system is opened and potentially reducing the infection risk." Therefore claims 19-26 and 29-36 are fully supported and described at least in the cited portions in the specification. For continuity and at the request of the examiner, the term delay was changed to interval in both the specification paragraph [0042]as well as in claim 32. This term as well as the term "delay" are clearly supported by the original specification.

The specification was objected to as failing to provide proper antecedent basis for the claimed subject matter. The specification paragraph [0014] was amended to indicate that volume reducer can comprise a volume reduction system. This is fully supported in the original specification.

Claims 5, 11-16, 18, 23-26, 30, and 31 were objected to noting informalities. Each of the cited informalities is corrected by amendment. This rejection is respectfully traversed.

Claims 19-26 and 29-36 were rejected under 35 U.S.C. 112 as failing to comply with the written description requirement. This rejection was discussed in the interview and has been addressed in the above remarks.

Claims 1-26, 28, and 29 were rejected under 35 U.S.C. 112 as being indefinite for failing to particularly point out and distinctly claim the subject matter. Each claim has been amended to address each cited point made by the examiner.

Claims 1-36 are rejected under USC 102(a) as being unpatentable over Ash (US Patent No.6,958,049) in view of Bierman (US Patent No.5,318,546). This was discussed in the interview and it was pointed out that Bierman teaches away from the present invention. For example, Bierman (as shown in Figure 1 of Bierman), discloses a device for attachment of an IV flow system with a connected "fluid supply container 14" and particularly Beirman discloses a device to urgently irrigate the catheter when flow in the IV line 18 ceases and to control the flow through the IV line 18. Bierman states, in Column 1 line 43 that "When the IV flow stops, blood clots may form and/or other organic debris may deposit on the distal end of the catheter cannula, thus clogging the catheter. Blood clotting occurs within 2 to 3 minutes after the IV flow ceases, and the clot increases in size thereafter." Further in column 3 line 49 Bierman states "The ratchet teeth/pawl interconnection of the interengaging element holds the band in several restricted positions as the pawl is adjusted over the ratchet teeth. Thus, the degree of tube

occlusion can be varied to **throttle the flow** through the catheter irrigation device or to substantially block the flow through the device." (emphasis added)

In contrast the device of the present invention is designed to sequentially reduce the volume of catheter extension tube wherein there is **no flow** from a fluid supply container. In Beirman (see figure 1) the proximal end of the "IV line 18" is connected to the "fluid supply container 14" whereas in Claim 1 states, "**the proximal terminal includes a seal for promptly sealing upon disconnection from the source so that a portion of the flush solution remains sealed within the tubing system** after the source has been disconnected from the systems thereby defining a residual flush solution within the tubing system". Claim 8 paragraph b states "...the volume reducer being configured for sequentially reducing the internal volume of the tube at a plurality of different times after the distal end has been connected with the catheter, the flush solution has been flowed into the space from the source, **and the source has been disconnected from the terminal"**. Claim 19 paragraph a reads "a patient mounted, **fluid-lock system** having a distal portion for insertion into a blood vessel to define an indwelling portion, the system having a single extension tube having an internal space defining an internal volume, the pressure within the space being essentially equal to the pressure in the blood vessel when the indwelling portion resides within the blood vessel, the system further having at least one proximal terminal for intermittent connection with an external fluid source of flush solution, **the proximal terminal including a seal for sealing upon disconnection of the source,** so that at least a portion of the flush solution entering the fluid-lock system through the terminal from the source remains sealed within the fluid-lock system after the source has been disconnected from the fluid-lock system, thereby defining a residual

volume of flush solution within the fluid-lock system," Claim 27 paragraph b reads "**a reservoir fluid-locked with the catheter for storing the mixture, the reservoir** being in fluid communication with a blood vessel through the lumen, the reservoir defining an internal space filled with the mixture, the space having an internal pressure essentially equal to the pressure within the blood vessel, such that the mixture within the lumen interfaces with blood within the blood vessel at a mixture-to-blood interface adjacent the distal end of the lumen," Claim 29 paragraph b reads "**a reservoir comprising a single extension tube fluid-locked with the catheter lumen for storing the flush solution**, the reservoir being in fluid communication with a blood vessel through the lumen, the reservoir defining an internal space substantially filled with the flush solution and the space having an internal pressure essentially equal to the pressure within the blood vessel, such that the flush solution within the lumen interfaces with blood within the blood vessel at a solution-to-blood interface adjacent the distal end of the lumen," Claim 30 paragraph b reads "flowing flush solution from the external fluid source, through at least one terminal and through the tubing system into the indwelling portion, at least a portion of the solution at least partially filling the internal volume, **promptly sealing the proximal terminal of the tubing system such that at least a portion of the flush solution remains sealed within the tubing system thereby defining a residual volume of flush solution within the tubing system**, and" Claim 31 paragraph c reads "**sealing the proximal terminal of the extension tube such that at least a portion of the flush solution remains sealed within the extension tube thereby defining a residual volume**

of flush solution within the extension tube, and" Claim 32 paragraph a reads "**injecting flush solution into the extension tube through the sealed proximal terminal to define**

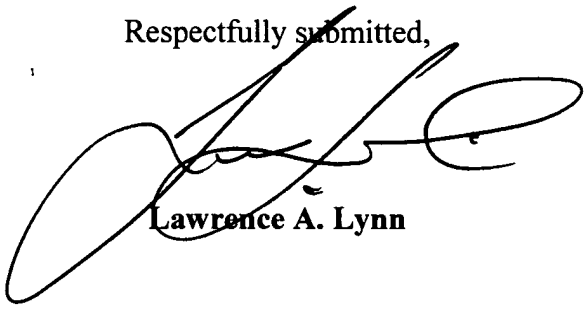
an initial volume of flush solution within the extension tube," Claim 35 reads " A method of maintaining the patency of a lumen of an indwelling catheter over a 24-72 hour period, the lumen being connected with a single **fluid locked extension tube** filled with flush solution, the extension tube defining an internal volume, the method comprising steps of; sequentially reducing the internal volume of the extension tube a plurality of different times to express sequential portions of the flush solution from the extension tube into the lumen to sequentially flush the lumen at a plurality of different times, wherein the steps of sequentially reducing comprises reducing the volume of the single extension tube a first time, to thereby define a first residual volume of the extension tube, and without refilling the extension tube, reducing the volume of the single extension tube a second time to thereby define a second residual volume of the extension tube, the second residual volume of the extension tube being less than the first residual volume of the extension tube."

The disclosure of Bierman therefore clearly teaches away from the present invention as claimed and withdrawal of the rejection under 35 103(a) is therefore respectfully requested.

It is respectfully submitted that this application is now, in condition for allowance.

Should the Examiner believe that anything further is desirable in order to place the application in even better form for allowance, she is respectfully petitioned to telephone the applicant at the below-listed number.

Respectfully submitted,



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